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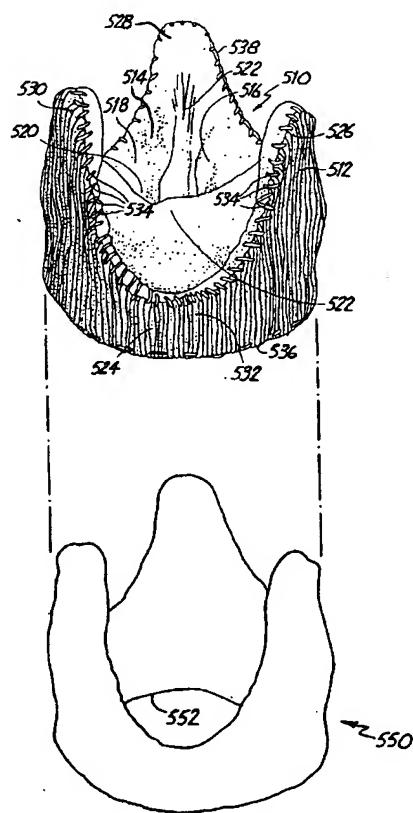
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(71) Applicant: ST. JUDE MEDICAL, INC. [US/US]; One Lillehei Plaza, St. Paul, MN 55117 (US).

(72) Inventor: BUCHANAN, Eric, S.; 4905 Tri Oaks Circle South, Wyoming, MN 55092 (US).

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(54) Title: TWO PIECE BIOPROSTHETIC HEART VALVE



(57) Abstract: A bioprosthetic heart valve (510) includes an outer frame (550) configured to attach to a tissue annulus of a heart and an inner bioprosthetic valve (510) having an exterior shape which substantially matches an interior shape of the outer frame (550). The exterior shape of the inner valve (510) mates in substantial alignment with the interior shape of the outer frame.

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## TWO PIECE BIOPROSTHETIC HEART VALVE

### BACKGROUND OF THE INVENTION

Implantable heart valves are used for replacement of defective valves in hearts of patients.

5      The valves are typically sutured to a tissue annulus that is left when the surgeon removes the existing valve from the patient's heart. The sutures are tied snugly, thereby securing the valve to the heart. Some two piece designs have been used, but they have typically been

10     limited to mechanical heart valves.

### SUMMARY OF THE INVENTION

A bioprosthetic heart valve includes an inner bioprosthetic valve and an outer frame configured to attach to a tissue annulus of a heart. An inner bioprosthetic valve has an exterior shape which substantially matches an interior shape of the outer frame. The exterior shape of the inner valve mates in substantial alignment with the interior shape of the outer frame. An outer frame-inner valve attachment mechanism is configured to couple the inner valve to the outer frame.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a bioprosthetic valve.

25     FIG. 2 is an exploded view of the valve of FIG. 1 and an outer frame.

FIG. 3 is a side cross-sectional view of an implantation device and the outer frame of FIG. 2.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

30     FIG. 1 is a perspective view of such a stentless bioprosthetic heart valve 510, such as the Toronto SPV® valve from St. Jude Medical. Valve 510 includes a covering 512 and is adapted for implantation

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in the aortic position. Valve 510 includes three leaflets 516, 518 and 520 which meet along coaptation surfaces 522. Covering 512 can comprise a flexible or fabric sheath which is contoured to the external surface 5 of the valve 510. In such an embodiment, covering 512 consists of a generally annular base 524 and three axially projecting and circumferentially-spaced commissure supports 526, 528 and 530. Sutures 534 along inflow edge 536 and outflow edge 538 are used to attach 10 covering 512 to valve 510. Covering 512 can be a biocompatible polymer such as polyester or polytetrafluoroethylene (PTFE).

FIG. 2 shows an exploded view of valve 510 and outer frame 550. Outer frame 550 has a shape which substantially matches the outer shape of valve 510 such that valve 510 fits securely within outer frame 550. Outer frame 550 can be secured to the native tissue annulus using any appropriate technique such as sutures, staples or screws, or other techniques. As outer frame 20 550 does not include the valve structure, it provides improved access to and visibility of the annular and sub-annular regions for the surgeon during the implantation procedure such that the orientation and location of the valve is more accurate. Outer frame 550 25 is a substantially flexible structure. In one embodiment, it is relatively thin, on the order of about 0.01 to about 0.05 inches (about 0.25 mm to about 1.27 mm), and is made from a flexible biocompatible polymer such as polyester or PTFE in a molded or fabric form. 30 The wall of outer frame 550 can be continuous, meshed, or have perforations.

After outer frame 550 has been implanted, valve 510 is attached to frame 550. This attachment can also be through suturing or other attachment techniques.

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In one embodiment, an adhesive is used to secure valve 510 to frame 550. For example, a chemically activated adhesive can be used in which the activating chemical is applied to outer frame 550 or valve 510 separately or  
5 combined together on either the frame 550 or valve 510 just prior to implantation. If an adhesive is used, a holder can be provided to hold the valve against frame 550 during the adhesion process. Preferably, the holder has a shape which substantially matches the shape of  
10 outer frame 550. Such a holder preferably maintains pressure between the valve 510 and the outer frame 550. For example, the holders can include an inflatable membrane similar to a balloon such that a force can selectively be applied from the valve 510 to the outer  
15 frame 550 while the adhesive cures.

These configurations allow the surgeon to use an adhesive without requiring the adhesive itself to be accurately applied to the native tissue during implantation. Further, as the adhesive will be placed  
20 on the frame 550 and/or valve 510, the adhesive will not drift into undesirable areas in the internal part of the valve such as the coronary ostia or into the left ventricle. A stronger and more consistent bond can be obtained because the adhesive will bond between similar  
25 materials as opposed to bonding the valve 510 directly to the native tissue. The invention reduces the time required to implant the valve, provides improved control of adhesive placement and improves bond reliability between similar materials.

30 A continuous or partial ridge 552 can be provided along the inflow edge of frame 550 to aid in the alignment and placement of valve 510 within frame 550. For example, the inflow edge 536 of valve 510 abuts ridge 552 when valve 510 has been accurately

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placed, and commissure supports 526, 528, 530 are in vertical alignment with the corresponding features of outer frame 550. Valve 510 can be rotated to the correct alignment before the adhesive cures. During 5 implantation, the inner valve 510 mates in substantial alignment with outer frame 550.

The outer frame 550 can be implanted using an implantation tool. For example, FIG. 3 is a side cross sectional view showing tool 211 carrying outer frame 550 at distal end 218. Screws 214 extend through outer frame 550 and can be used to attach outer frame 550 to the native tissue annulus as discussed above. Although FIG. 3 illustrates screws 214 located in a single plane near the inflow edge of outer frame 550, additional screws can be positioned at other locations on frame 550 to provide improved attachment. In such an embodiment, additional flexible shafts can be provided to simultaneously actuate additional screws. Screws 214 are actuated by actuating handle 224 and shaft 222 relative to housing 220. For example, a gearing mechanism can turn flexible shafts 262 and thereby rotate screws 214. Once the valve 510 is coupled to outer frame 550, the heads of screws 214 are covered by valve 510 and secured in place. Sutures or staples can also be used to implant outer frame 550. In one aspect, 25 any type of surgical attachment mechanism can be used to implant outer frame 550.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from 30 the spirit and scope of the invention.

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WHAT IS CLAIMED IS:

1. A bioprosthetic heart valve, comprising:
  - an outer frame configured to attach to a tissue annulus of a heart;
  - an inner bioprosthetic valve having an exterior shape which substantially matches an interior shape of the outer frame, the exterior shape of the inner valve mating in substantial alignment with the interior shape of the outer frame; and
  - an outer frame-inner valve attachment mechanism configured to couple the inner valve to the outer frame.
2. The bioprosthetic heart valve of claim 1 wherein the outer frame-inner valve attachment mechanism comprises an adhesive.
3. The bioprosthetic heart valve of claim 1 including an outer frame attachment mechanism configured to couple the outer frame to tissue of the heart.
4. The bioprosthetic heart valve of claim 3 wherein the outer frame attachment mechanism comprises a plurality of screws.
5. The bioprosthetic heart valve of claim 1 wherein the outer frame includes a polymer.
6. The bioprosthetic heart valve of claim 1 wherein the outer frame inner valve attachment mechanism comprises a suture.

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7. The bioprosthetic heart valve of claim 3 wherein the outer frame attachment mechanism comprises a suture.
8. The bioprosthetic heart valve of claim 1 wherein the outer frame includes a ridge on an interior surface of the outer frame, and the inner bioprosthetic valve abuts the ridge.
9. The bioprosthetic heart valve of claim 1 wherein the outer frame is flexible.
10. The bioprosthetic heart valve of claim 1 wherein the outer frame and inner valve are of similar materials.

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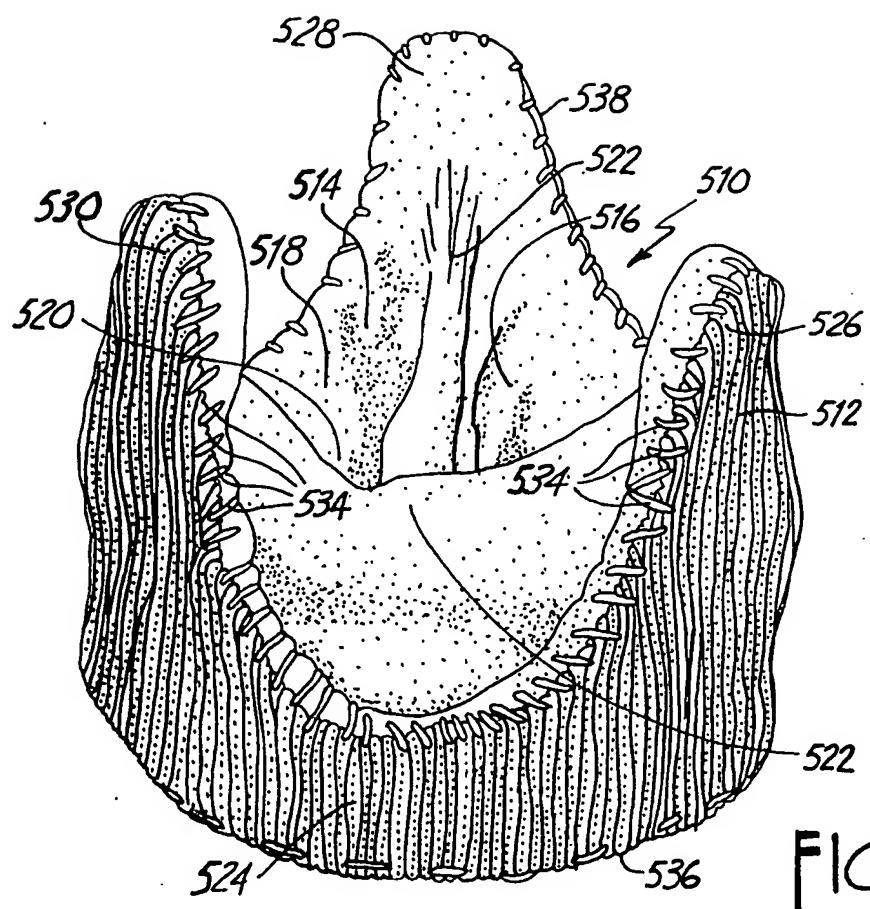


FIG. 1

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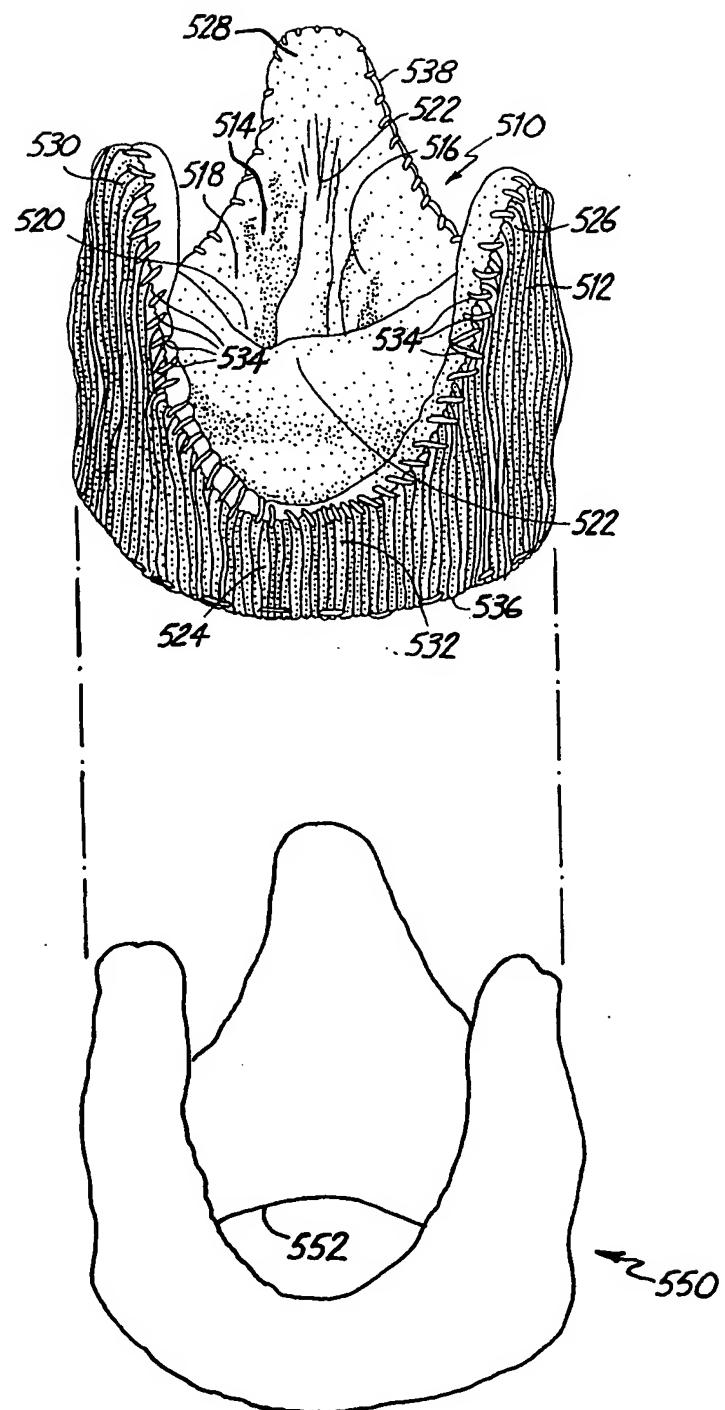


FIG. 2

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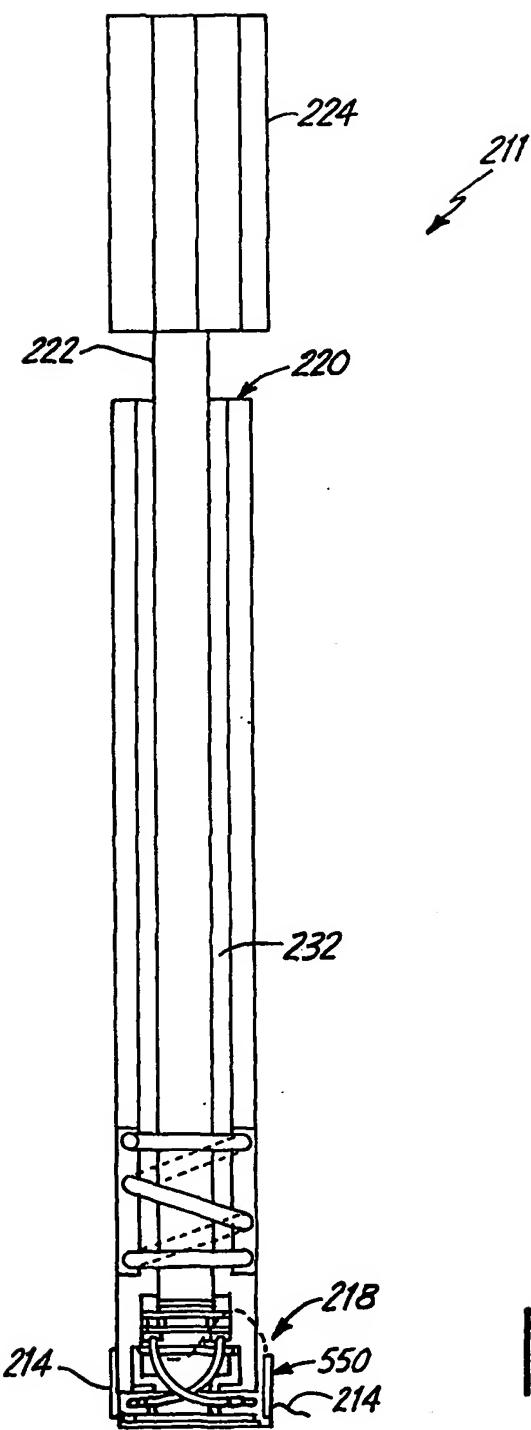


FIG. 3